

1 IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
2 BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

3
4 ERIC A. FORSSSEN)

5 v.)

6 ROLF J. MEHLHORN)

Interference No. 103,469

Administrative Patent Judge:
Ronald H. Smith

7
8 Tuesday, May 13, 1997

9 Washington, D. C.

10 Deposition of:

ORIGINAL

11
12 JAMES H. PRESTEGARD

13
14 a witness, called for examination by counsel for the
15 parties, pursuant to notice of counsel, held at the
16 offices of Finnegan, Henderson, Farabow, Garrett &
17 Dunner, L.L.P., 1300 I Street, N.W., Suite 700,
18 Washington, D. C., in Conference Room 8-B
19 beginning at 10:03 a.m., before Richard B. Whalen,
20 Registered Merit Reporter and Notary Public in and
21 for the District of Columbia, when were present on
22 behalf of the respective parties:

PRESTEGARD, JAMES H.

For Party Eric A. Forssen:

JERRY D. VOIGHT, ESQ.
JEAN BURKE FORDIS, ESQ.
Laurel Boone, Technical Specialist
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<u>DEPOSITION EXHIBITS:</u>	<u>ID</u>
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NONE

ATTACHMENT - Forssen Notice Under 37 C.F.R. 1.673(e)
Dated April 28, 1997

PRESTEGARD, JAMES H.

P R O C E E D I N G S

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MR. VOIGHT: This is the cross-examination of the deposition in Interference Number 103,469, Forssen versus Mehlhorn, of Dr. James Prestegard.

In accordance with the rules, we will need a certified copy of the deposition that includes in it, bound to it the Notice of Deposition.

I'm asking the reporter, do you have a copy of the Notice of Deposition to include?

THE OFFICIAL REPORTER: No, sir.

MR. VOIGHT: I don't have one with me at the moment, but I will provide you with one before we quit today.

I think we dealt with all of this stuff before, Danny. Let's run through it again. Under Rule 673, we are responsible for filing a certified transcript, seeing that it is done, although -- in accordance with Rule 676, which provides that the reporter files the certified transcript unless the parties agree in writing.

I think we agreed that we could do it with

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1 regard to the Nichols d position. Is it all right
2 again if we do it with regard to Prestegard?

3 MR. HUNTINGTON: Yes, it is.

4 MR. VOIGHT: Then also, let's see, that
5 needs to be done within 45 days, which we can do.
6 There are also service requirements for service on
7 you and since the time for the record will fall due
8 so close to the time any service is due, may we do
9 that and accomplish that by serving on you our
10 record?

11 MR. HUNTINGTON: Yes.

12 MR. VOIGHT: I guess last, we did agree to
13 signing before any notary with Dr. Nichols. I
14 assume that's all right also for Dr. Prestegard.

15 MR. HUNTINGTON: Yes, it is.

16 MR. VOIGHT: Have I forgotten anything?

17 MR. HUNTINGTON: Nothing that comes to
18 mind. One thing I would note before we start this
19 is that the copy of the declaration that you have
20 filed with the pages numbers at the bottom is
21 missing a page.

22 MR. VOIGHT: We pick d that up. There is

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1 a page missing.

2 MR. HUNTINGTON: I assume that in the
3 record you will simply insert that with an A or
4 something.

5 MR. VOIGHT: Yes. I think we will call
6 that 22-A or whatever it needs to be.

7 MR. HUNTINGTON: I was just getting at
8 that that was a mistake and not a desire to leave
9 that page out.

10 MR. VOIGHT: You're absolutely correct.
11 It was a mistake and we intend to reinsert it if we
12 may.

13 MR. HUNTINGTON: That's not a problem.
14 Would you swear the witness, please

15 Thereupon,

16 JAMES H. PRESTEGARD
17 a witness, called for examination by counsel for the
18 parties, and, after having been sworn by the notary,
19 was examined and testified as follows:

20 EXAMINATION BY COUNSEL FOR PARTY

21 ROLF J. MEHLHORN

22 BY MR. HUNTINGTON:

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1 Q Would you state your name for the record,
2 please?

3 A James Prestegard.

4 Q What is your current employment address?

5 A Yale University, Chemistry Department, New
6 Haven, Connecticut. Do you need the zip code? It's
7 06520.

8 Q Are you still a tenured professor of
9 chemistry at Yale?

10 A Yes.

11 Q On your first declaration in this
12 proceeding, you have a home address in North Haven.
13 Is that still your home address?

14 A It's still my home address.

15 Q Did you do anything to prepare for today's
16 deposition?

17 A Yes.

18 Q What did you do?

19 A I reviewed certainly my own declaration, a
20 number of the papers that are referred to in that
21 declaration. We've had discussions with counsel
22 here from Finnegan, Henderson.

1 Q Did you look at any documents as part of
2 preparing for this deposition that you did not look
3 at as part of preparing your declarations?

4 A Yes, actually.

5 Q What did you look at?

6 A There is -- there was an additional, it
7 may have been more than one additional background
8 reference that I was curious about referred back
9 to --

10 Q I'm sorry?

11 A Referred back to some additional
12 literature.

13 Q Did you -- are you aware that Dr. Nichols'
14 deposition was taken last week?

15 A Yes.

16 Q Did you look at the transcript of that
17 deposition?

18 A No.

19 Q You understand what I mean by a
20 transcript, in other words, the record like that's
21 being prepared today here?

22 A I saw both of you just discuss an issue in

1 that transcript, so, yes, I know what it is.

2 Q Were you told what was in that
3 transcript?

4 A No.

5 Q Were you told what kinds of questions I
6 might be asking?

7 A Some types of questions were suggested.

8 Q How much time did you spend doing that?

9 A Oh, let's see. I would guess about four
10 hours.

11 Q How long overall did you spend meeting
12 with attorneys from Finnegan, Henderson?

13 A From my initial involvement in this?

14 Q No, to prepare for the deposition today.

15 A Maybe five, five to six hours.

16 Q When did that occur?

17 A Yesterday afternoon and into the evening.

18 Q Have you had any training as a patent
19 attorney?

20 A No.

21 Q Have you ever had any training with
22 respect to patents?

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1 A No.

2 Q Looking at your first declaration, I think
3 you have a copy of it in front of you, you said you
4 had reviewed this again as a part of preparing for
5 this deposition, right?

6 A Yes.

7 Q If you look at the last page, it has a
8 page number 21 on it, it shows a signing date of
9 February 24, '95; is that right?

10 A That's correct.

11 Q When this declaration was first prepared,
12 you didn't write it, did you?

13 A I didn't write this final copy, no.

14 Q A draft was prepared and sent to you for
15 your review, right?

16 A Yes.

17 Q And then you made changes and went through
18 at least another draft before signing?

19 A Yes.

20 Q Do you recall how many drafts there were?

21 A I don't recall. I know that it was more
22 than one, I mean, I know there was a draft. I don't

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1 remember the exact number.

2 Q Do you remember how significant -- let me
3 start that question again.

4 Do you remember how many changes were made
5 between the first draft and the final draft?

6 A No, I don't remember that.

7 Q Were there a number of changes?

8 A I remember there were a number of
9 changes. I think there were some deletions and some
10 changes, but I just don't remember the specifics.

11 Q Were there things that you disagreed with
12 in the first drafts that you wanted removed?

13 A I don't remember disagreements. I think
14 it was more a matter of wording that I didn't think
15 was optimal.

16 Q Do you know what the word "anticipated"
17 means in a patent law context?

18 A I don't know for sure in a patent law
19 context.

20 Q What do you understand it to mean?

21 A I understand "anticipated" to mean that by
22 examining a paper, for example, that one would have

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1 be n able to -- I'm trying to find another word for
2 "anticipate" -- but to see that certain related set
3 of experiments were derivative or directly related.

4 Q Do you know what "obvious" means in a
5 patent law context?

6 A Again, I don't know what it means in a
7 patent law context.

8 Q What does it mean to you?

9 A To me, "obvious" would mean that someone
10 who is working regularly in a specialized field
11 would read something and draw a conclusion rather
12 readily and quickly from stated material.

13 Q How would you describe your field that you
14 are a person skilled in the art in the time period
15 from, say, 1975 to 1985?

16 A My field, you know, as opposed to this
17 specific area of my former publications that are
18 cited here, I would describe as membrane biophysical
19 chemistry.

20 Q Have you ever done any in vivo studies of
21 liposomes?

22 A In vivo, no.

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1 Q I want you to look at your curriculum
2 vitae that was one of the exhibits that was
3 submitted to the Patent Office.

4 Do you have a copy of that?

5 A I wonder if that's here.

6 MR. VOIGHT: Yes, it should be.

7 THE WITNESS: Yes, it is.

8 BY MR. HUNTINGTON:

9 Q I would like you to look at the third page
10 of that. Under Current Research Interests, you
11 indicate that this is -- that they include the study
12 of the structure and dynamics of systems of
13 biological interests through the use of nuclear
14 magnetic resonance spectroscopy; is that correct?

15 A That's right.

16 Q A great deal of your research has dealt
17 with that, hasn't it?

18 A Yes.

19 Q And in fact, the paper that's cited as a
20 part of these proceedings here is a paper dealing
21 with NMR; is that right?

22 A That's correct.

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1 Q When you get to the part about the systems
2 currently under study, this is your description of
3 what you were doing at the time this particular CV
4 was prepared in '94 and '95, right?

5 A Yes.

6 Q You would agree, wouldn't you, that most
7 of your publications deal with NMR?

8 A Yes.

9 Q You'd also agree that you're not an expert
10 in drug delivery, wouldn't you?

11 A An expert? I do not prepare media for
12 drug delivery, so I think that's an accurate
13 statement. I wouldn't consider myself an expert in
14 drug delivery.

15 Q I'm sorry, you wouldn't?

16 A I would not consider myself an expert in
17 drug delivery.

18 Q And that goes not only for the current
19 time but back in the 1975 to the '85 time period,
20 right?

21 A Yes.

22 Q I'd like to talk a little bit now about

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1 your own publication here that was marked as an
2 exhibit.

3 Do you have a copy of that?

4 A Yes.

5 Q This particular paper is concerned with
6 the pH-induced transport of fumaric and maleic
7 acids, right?

8 A Correct.

9 Q Neither of those are drugs, are they?

10 A That's correct. Not to my knowledge, at
11 least.

12 Q What you were studying here was the
13 transport of these particular materials across a
14 lipid layer, right?

15 A Yes.

16 Q It's also true that the spectra that you
17 acquired in the study were done in less than 70
18 seconds, right?

19 A Yes, I believe that's stated in the
20 paper.

21 Q After the fumaric acid was concentrated in
22 the liposomes, then there was a leakage back out,

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1 right?

2 A That's correct.

3 Q Now, you weren't -- you were simply
4 looking at transport of molecules, not -- you
5 weren't looking to maintain a drug in a liposome,
6 right?

7 A Well, the -- I mean, in the sense that
8 fumaric acid and maleic acid are not drugs, we were
9 not concerned with the containment of the drug. We
10 did monitor, as you indicated, the leakage of these
11 compounds over time.

12 I'm not sure I understand your question.

13 Q I think you answered it sufficiently for
14 my purposes, at least.

15 A Okay.

16 Q You also refer to a paper by Fendler. Do
17 you recall that?

18 A Yes.

19 Q Now, Fendler doesn't use a gradient to
20 load the liposomes, does it?

21 A No.

22 MS. FORDIS: Do you have a copy of Fendler

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1 available?

2 MR. VOIGHT: It should be there.

3 BY MR. HUNTINGTON:

4 Q I'd also ask you to simply confirm that
5 Fendler does not mention your work nor the work of
6 Dr. Nichols; is that right?

7 A I believe that is correct. That's
8 correct.

9 Q Now, going back to the Nichols paper that
10 you have discussed in your declarations, it does not
11 teach loading and retention of material in liposomes
12 over time, does it?

13 MR. VOIGHT: Do you want to look at that
14 paper?

15 THE WITNESS: I've got it. I would say
16 that it does.

17 BY MR. HUNTINGTON:

18 Q Well, when you look at the Figure 1, you
19 see that it looks at loading --

20 A It looks at time course of loading, yes.

21 Q Right, but when it reaches a maximal
22 level, the pH is changed and there is no attempt to

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1 see how long the material would stay in the
2 liposome, right?

3 A That's correct. It is in 90 minutes where
4 that is done and it appears to have reached a
5 plateau.

6 Q But there is no attempt to see whether it
7 would maintain that plateau, right?

8 A There is no attempt to see that beyond 90
9 minutes.

10 Q Are you aware of what the purpose of the
11 Nichols paper was?

12 A My recollection is that it was an
13 investigation of a mechanism for the uptake of
14 biogenic amines.

15 Q So it was attempting to determine what
16 happened in vivo for the uptake of these particular
17 materials?

18 A It was the construction of a model system
19 that mimicked an in vivo process.

20 Q The paper was not concerned with
21 maintaining an entrapped drug, was it?

22 A My reading is that that was not the intent

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1 or at least from my reading, I wouldn't conclude
2 that was the intent.

3 Q Do you know whether the amount of drug
4 loaded into the liposomes in the Nichols paper would
5 be useful for therapeutic purposes?

6 A I would not know what the appropriate
7 levels for a particular drug -- I don't know what
8 levels a particular drug would be required for
9 therapeutic application.

10 Q I wonder if you would look at your second
11 declaration. And specifically, I'd like for you to
12 look at paragraph 4.

13 If you look at the last sentence of that
14 paragraph, you say that you believe that one skilled
15 in the relevant art would have extrapolated loading
16 of other specific drugs into liposomes from Nichols'
17 initial description of the mechanism of loading the
18 drugs dopamine and norepinephrine into liposomes by
19 means of a pH gradient, right?

20 A Yes.

21 Q And yet you say you don't know whether the
22 amount of material that Nichols loaded was a

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1 therapeutic -- was us ful for therapeutic purposes,
2 right?

3 A Right.

4 Q So isn't it true that if Nichols loaded
5 such small amounts that it wouldn't be useful for
6 therapeutic purposes that other people wouldn't have
7 been led from that to try liposomes with other
8 drugs?

9 A No, I don't think that's correct because
10 the amount of drug loaded is a function of how one
11 does that experiment. It's a function of the pH
12 gradient. It's not a defined limit.

13 Q Well, but Nichols has certainly relatively
14 small amounts of drug loaded, doesn't it?

15 A I don't remember the exact amounts without
16 referring --

17 Q You can certainly refer to it. I think
18 you'll find that the amounts are between 12- and
19 23-fold.

20 MR. VOIGHT: I would just note that seems
21 to be relative, not absolute.

22 THE WITNESS: Yes. I believe those are

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1 the correct numbers for the ratio, but it is in fact
2 the final concentration that's relevant, not degree
3 of con -- not the degree of loading or the factor of
4 loading.

5 BY MR. HUNTINGTON:

6 Q Okay. But in this particular case, it was
7 maximal loading, right, that was the point at which
8 they agreed to reach the maximal loading?

9 A Under -- under the conditions of the
10 experiment, yes.

11 Q So what you're saying is that this would
12 have encouraged other people to try this particular
13 procedure to see if additional drug could be loaded,
14 right?

15 A Yes.

16 Q So looking at the way you described
17 "obvious" before, you would say looking at this
18 paper it would be obvious for people skilled in the
19 art to try to --

20 MR. VOIGHT: I object to that question.
21 It's very unfair and misleading. You're using
22 patent law terms on him that h 's already indicated

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1 he doesn't know the definition of. H 's not a
2 lawyer. He's not aware of the implications of that
3 question.

4 MR. HUNTINGTON: I'm asking him only in
5 his own words. If he doesn't like those words,
6 then --

7 MR. VOIGHT: I would also object to the
8 question as totally mischaracterizing his prior
9 testimony.

10 BY MR. HUNTINGTON:

11 Q Okay. Do you understand the question?

12 A No.

13 Q Okay. Aren't you saying that from looking
14 at Nichols and Deamer that a person skilled in the
15 art, that it would be obvious to them to try to load
16 liposomes with drugs?

17 A Certain types of drugs, yes.

18 Q Well, in fact, you say in the prior
19 paragraph of your declaration that, in the sentence
20 that's bridging the two pages, in the case of
21 liposome loading, there are many issues relating to
22 permeability and ionization that may vary somewhat

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1 from compound to compound, right?

2 A Yes.

3 Q So until you do a particular experiment
4 with a particular drug, you don't know whether it
5 can be loaded effectively or not, right?

6 MR. VOIGHT: Hold on a minute. I want to
7 look at the question.

8 (Pause.)

9 MR. VOIGHT: I'm just ask the reporter to
10 read the question back.

11 (The reporter read back the portion requested.)

12 THE WITNESS: I mean, it really depends on
13 the relationship of drugs to compounds that have
14 been previously examined.

15 There's a range of compounds which someone
16 skilled in the area could make reasonable
17 predictions about the behavior. There are
18 certainly, as I state, factors that might be outside
19 of the bounds of reasonable extrapolation.

20 BY MR. HUNTINGTON:

21 Q In the last sentence in paragraph 4 of
22 your declaration that we just talked about, when

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1 you're saying of loading of drugs into liposomes,
2 you're not necessarily saying that they can be
3 loaded at therapeutic levels, are you?

4 A Well, since I -- that, of course, varies a
5 great deal from drug to drug, and I don't know a
6 sufficient amount about therapeutic levels of drug
7 administrations to answer that.

8 Q So if you don't know what therapeutic
9 levels are, how can you know what Nichols would --

10 MR. VOIGHT: Objection.

11 BY MR. HUNTINGTON:

12 Q -- to a person skilled in the art?

13 MR. VOIGHT: Objection. That's not
14 characterizing his prior testimony either.

15 MR. HUNTINGTON: Would you read the
16 question back, please?

17 (The reporter read back the portion requested.)

18 MR. VOIGHT: Could you -- I apologize, but
19 I have the objection right in the middle. Could you
20 rephrase the question? I'll let you finish before I
21 make my objection.

22 BY MR. HUNTINGTON:

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1 Q All right. You said that you don't know
2 what therapeutic levels are for the particular drugs
3 that are in the Nichols paper, right?

4 A That's -- that's what I said, yes.

5 Q Now, if you don't know what the
6 therapeutic levels are, how can you know what
7 Nichols would teach to a person skilled in the art?

8 MR. VOIGHT: Object. I mean, again you
9 started this on the basis of what he says in
10 paragraph 4 of his declaration. Now it's moved
11 totally away from that and really bears no
12 relationship at all to this statement that appears
13 in his prior declaration.

14 You may answer if you can.

15 THE WITNESS: The -- well, let me put it
16 this way: The level of therapeutic administration
17 is not a simple function of how much drug is in the
18 liposomes, because there you're talking about how
19 much of the liposome preparation you actually
20 administer. All right.

21 So in general in the liposome field, the
22 higher the concentration of drug that one can

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1 achieve in the liposom , the better. And one simply
2 adjusts the amount administered to reach a
3 therapeutic level.

4 BY MR. HUNTINGTON:

5 Q I'd like for you to look at the Mayer
6 paper that you referred to in your declaration.
7 This is Forssen Exhibit 15.

8 MR. VOIGHT: You may not have that one.
9 I'm not sure. It should be the last one in the
10 stack if it's there.

11 THE WITNESS: Yes.

12 BY MR. HUNTINGTON:

13 Q Now, if you look at the first paragraph --
14 well, the first thing, this was published in 1985,
15 right?

16 A Yes.

17 Q So that's eight years after Nichols and
18 Deamer, right?

19 A Yes, eight or -- Nichols and Deamer
20 was '76, so it's eight or nine.

21 Q Okay. And it's eight years after your
22 publication, right?

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1 A Yes.

2 Q The first paragraph reads: Liposomal
3 carrier systems have significant potential for the
4 in vivo delivery of encapsulated drugs. However,
5 many difficulties remain before this potential can
6 be realized.

7 Particular problems include the efficient
8 production of an appropriate liposomal carrier,
9 efficient encapsulation and retention of drugs of
10 biological interest, developing methods to avoid
11 nonspecific uptake by the reticuloendothelial
12 system, and mechanisms to target the carrier to
13 specific tissue.

14 These are all major problems and it is
15 clear that a logical step-by-step development is
16 required before successful delivery can be
17 achieved.

18 Do you agree that that was true in 1985?

19 A It's clear that a logical step-wise
20 development is required. Yes, I'd have to say that
21 to prepare a particular liposomal drug delivery
22 system is -- requires a number of steps and the

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1 resolution of a number of problems.

2 Q And that liposomal carrier systems still
3 had major problems as of 1985, do you agree with
4 that?

5 A Yes, I would agree with that.

6 Q And yet you're saying that these
7 publications back in '77 -- '76 and '77 make it
8 obvious to use liposomal systems for drug delivery?

9 Is that what you're saying?

10 MR. VOIGHT: I don't know that he said
11 that. He said that he makes -- what his correct
12 characterization is. You keep mischaracterizing his
13 testimony in a way I think is absolutely
14 unconscionable.

15 What he says is it makes obvious what
16 Forssen disclosed in claim -- Mehlhorn has disclosed
17 in claim. He's not even connected to a drug
18 delivery system, for heaven's sake.

19 BY MR. HUNTINGTON:

20 Q Do you agree with what your counsel just
21 said?

22 A Yes.

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1 Q Actually I shouldn't. I don't know if
2 he's your counsel or not, but what Mr. Voight said?

3 A Yes.

4 Q So you're not taking any position on --
5 you have not taken any position on drug delivery,
6 you're simply talking about the loading of chemicals
7 into liposomes; is that right?

8 A Yes, by a particular mechanism.

9 MR. VOIGHT: I think that actually again
10 is where you mischaracterized his testimony because
11 he certainly has testified previously in what you
12 were just asking about that it extrapolates the
13 loading of other specific drugs, or more precisely,
14 I believe that one skilled in the relevant art would
15 have extrapolated loading of other specific drugs
16 into liposomes from the Nichols initial description,
17 et cetera. That's in paragraph 4, page 24 of his
18 prior declaration.

19 BY MR. HUNTINGTON:

20 Q Have you read the Forssen patent that's
21 involved in this interference?

22 A Yes, a number of years ago.

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1 Q Did you review it as a part of preparing
2 for this deposition?

3 A I did not review that patent.

4 Q Are you aware of the fact that the
5 application that ultimately became the Forssen
6 patent was filed two years after the Mehlhorn
7 application that's involved in this interference?

8 A I don't know the exact dates. It is my
9 recollection that it was filed after.

10 Q And you're also aware that the -- that
11 Forssen has taken the position in this proceeding
12 that the claims that it had originally obtained from
13 the Patent Office with a couple of exceptions are
14 invalid, right?

15 MR. VOIGHT: Objection. This is totally
16 beyond the scope I think of any of his direct
17 testimony and therefore it's improper.

18 BY MR. HUNTINGTON:

19 Q Do you understand the question?

20 A Yes. I understand -- I understand the
21 question, yes.

22 Q Okay. Do you know the answer to the

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1 question?

2 A Yes, that's my -- would you repeat it
3 again, please?

4 Q Okay. You realize that the claims that
5 Forssen originally argued and obtained from the
6 Patent Office in the Forssen patent as a part of
7 this interference, they have said that those claims
8 are unpatentable with a couple of exceptions?

9 MR. VOIGHT: Who is "they"?

10 MR. HUNTINGTON: Forssen has said that.

11 MR. VOIGHT: I'm not sure that -- I'm not
12 sure that I agree with that, but that's all right.
13 Same objection, though, on the ground of beyond the
14 scope of direct.

15 And if you need the question read back
16 again, we'll get it read back.

17 MR. HUNTINGTON: Let me try one more time.

18 MR. VOIGHT: Before you do it, so I won't
19 have to interrupt, may I have an objection?

20 MR. HUNTINGTON: Yes. You may have an
21 objection, continuing objection to any questions
22 about the Forssen patent.

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1 MR. VOIGHT: All right. Thank you.

2 THE WITNESS: I guess I need to have it
3 read again.

4 BY MR. HUNTINGTON:

5 Q I'll repeat it. You understand that
6 Forssen argued for and obtained certain claims from
7 the Patent Office that are seen in the Forssen
8 patent, right?

9 A Yes.

10 Q And you understand that in this
11 interference, Forssen said that most of their claims
12 were invalid, right?

13 A I guess I'm a little confused by what you
14 mean by "this interference."

15 Q The proceeding that your declaration is
16 filed in.

17 A I have trouble identifying the particular
18 document that this appears in. That general
19 characterization is consistent with my
20 understanding.

21 Q Well, you remember that you have
22 appendices attached to your -- charts attached to

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1 your declarations. For instance, your second
2 declaration has a chart 4 that says obviousness of
3 claims 51 through 55, right?

4 A Right.

5 Q And you said that you read the papers
6 associated the motions, et cetera?

7 A Yes.

8 Q And do you recall that in those papers,
9 Forssen said that most of their claims, and I can
10 read the numbers if you want, but most of their
11 claims would not be patentable over this art,
12 right?

13 A That is my recollection, yes.

14 Q Now, your paper was one of the documents
15 given to the Patent Office by Forssen, right?

16 A I believe that's correct.

17 Q And Forssen still took the position while
18 they were getting their patent that these claims in
19 their patent were patentable over your paper,
20 right?

21 A Actually --

22 MR. VOIGHT: How does he possibly know the

PRESTEGARD, JAMES H.

1 answer to that question?

2 MR. HUNTINGTON: I'm asking him does he
3 know.

4 THE WITNESS: I actually was not involved
5 in those early proceedings and so I don't know a lot
6 of details about that.

7 BY MR. HUNTINGTON:

8 Q Have you looked at the papers that were
9 filed in the Patent Office by Forssen?

10 A Yes.

11 MR. VOIGHT: Which papers are you
12 referring to?

13 MR. HUNTINGTON: The papers to obtain the
14 Forssen patent.

15 THE WITNESS: I did that a couple of years
16 ago. I have not looked at them in the last few
17 days.

18 BY MR. HUNTINGTON:

19 Q Nichols and Deamer, the publication, that
20 particular study, they were not using the
21 epinephrine and related compounds because they were
22 drugs, were they?

PRESTEGARD, JAMES H.

1 A Because they were drugs?

2 Q I mean, there were simply --

3 A No, I would say --

4 MR. VOIGHT: Again, how can he know what
5 motivated? Objection. You're asking him to
6 speculate on the motivations of Nichols and Deamer.
7 How can he possibly know what motivated them or if
8 that was a factor they took into account?

9 BY MR. HUNTINGTON:

10 Q They don't refer to them as being drugs,
11 do they?

12 A I don't recall a specific characterization
13 of those as drugs; however, people in the area would
14 certainly identify things like dopamine and
15 epinephrine as drugs.

16 MR. HUNTINGTON: Let's take a break here.
17 I only need about five minutes.

18 (Pause.)

19 MR. HUNTINGTON: I have no further
20 questions.

21 MR. VOIGHT: I've got a little bit of
22 redirect.

PRESTEGARD, JAMES H.

EXAMINATION BY COUNSEL FOR PARTY

ERIC A. FORSSEN

BY MR. VOIGHT:

Q First, let's turn to Forssen Exhibit 5, Dr. Prestegard. That's your paper. Do you have that in front of you?

A Yes.

Q Was there a sponsor for the research that's reflected by that paper?

A Yes.

Q Who was the sponsor?

A National Institutes of Health.

Q Do you know if at any time the National Institutes of Health recognized that your work had application to drug delivery systems?

A Yes. That was used as the justification for funding, or request for funding.

Q Okay. Now, also, I'm switching to a new topic, during your cross-examination, you were asked or the question was something to the effect that you were not looking to maintain a drug in a liposome.

And at least part of your answer that you

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1 gave indicated that your work included monitoring
2 leakage.

3 Do you remember that testimony I've just
4 referred to?

5 A Yes.

6 Q Okay. Now, then, in connection with the
7 work reflected by Forssen Exhibit 5, did you observe
8 accumulation of, say, fumaric acid inside the
9 liposome?

10 A Yes.

11 Q Was the fumaric acid entrapped in the
12 liposome?

13 A Yes.

14 Q With regard to stability, how would you
15 characterize the liposome you obtained following the
16 work in your paper of Forssen Exhibit 5?

17 Let me read that. I think that's fine.

18 MR. VOIGHT: Could you read the question
19 back to the witness?

20 (The reporter read back the portion requested.)

21 MR. HUNTINGTON: Objection. Outside the
22 scope of cross-examination.

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1 THE WITNESS: Answer? I would
2 characterize it as being -- exhibiting stability,
3 that that is typical of liposome preparations in a
4 useful range.

5 MR. VOIGHT: I do think it was fairly
6 within the scope of cross, but I don't see any
7 reason to debate that here.

8 BY MR. VOIGHT:

9 Q You were also asked some questions with
10 regard to the Nichols paper and about not, I think,
11 maintaining the loaded liposomes, something to that
12 effect.

13 Do you recall such testimony during
14 cross?

15 A Yes, I recall testimony involving changing
16 or abolishing the pH gradient at roughly 90
17 minutes.

18 Q Right. Based on your review of the
19 Nichols work that's reported in Forssen Exhibit 3,
20 do you have any opinion as to whether or not he
21 obtained a stable liposome with an enhanced or
22 accumulated content of catecholamines?

1 A Yes.

2 Q What is your opinion?

3 A Again, that preparation exhibits stability
4 over the period of in this case roughly 90 minutes.

5 Q Now, again changing to a slightly
6 different topic, you were also asked some questions
7 about I think both the Nichols work and your own
8 work with regard to the amount of the chemical
9 species that was accumulated or entrapped inside the
10 liposome.

11 Do you remember that?

12 A Yes.

13 Q Is there in your -- do you have an opinion
14 with regard to whether or not the Mehlhorn patent
15 application specification teaches anything with
16 regard to obtaining larger amounts of the chemical
17 species that is desired to be entrapped that is not
18 taught in either your paper, which is Forssen
19 Exhibit 5, or in Nichols paper, which is Forssen
20 Exhibit 3?

21 A No, I do not see anything beyond what is
22 taught in the -- some of those papers referenced.

PRESTEGARD, JAMES H.

1 Q Do you have an opinion with regard to
2 whether or not the Mehlhorn patent specification
3 teaches anything that permits obtaining stable
4 liposomes having an enhanced concentration of the
5 desired chemical species within the liposome that is
6 not disclosed in your paper, that is Forssen
7 Exhibit 5, or the Nichols paper, that is Forssen
8 Exhibit 3?

9 A No. I saw nothing that describes a method
10 that addresses any enhancement over stability
11 obtained in the previous papers.

12 MR. VOIGHT: I would like a couple
13 minutes. I'm going to ask you to stay here.

14 THE WITNESS: Okay.

15 (Pause.)

16 MR. VOIGHT: Actually we have no more
17 questions.

18 MR. HUNTINGTON: Then we're done.

19 MR. VOIGHT: Let me make a brief statement
20 on the record. You will get a subsequently,
21 Dr. Prestegard, a copy of the transcript of the
22 deposition you've given today and it will include an

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1 errata sheet.

2 We would like you to review it carefully
3 and note any errors. And then after the errors have
4 been noted and you have filled out the errata sheet,
5 you need to sign the deposition transcript before a
6 notary, but it can be any convenient notary.

7 THE WITNESS: All right.

8 MR. VOIGHT: And send it back.

9 MR. VOIGHT: Also that does need to be
10 done promptly because we have to file them in the
11 Patent Office.

12 I would like the record to reflect that I
13 have now given the reporter a copy of the Notice of
14 Deposition for inclusion in the certified copy of
15 the transcript.

16 (Reading and signature not waived.)

17 (Whereupon, the deposition was concluded
18 at 11:04 a.m.)

19 I have read the foregoing pages
20 1 - 40 inclusive, which contain a
21 correct transcript of the answers
22 made by me to the questions therein
recorded.


JAMES H. PRESTEGARD

MY COMMISSION EXPIRES
Jun 5/97

SHERRY ROE & ASSOC., INC.

PRESTEGARD, JAMES H.

1 UNITED STATES OF AMERICA)

2)

3 DISTRICT OF COLUMBIA)

4 I, Richard B. Whalen, the officer before
5 whom the foregoing proceedings were taken, do hereby
6 certify that the proceedings were taken
7 stenographically by me and thereafter reduced to
8 typewriting under my direction; that said transcript
9 is a true and accurate record of the proceedings
10 herein to the best of my knowledge and belief; that
11 I am neither counsel for, related to, nor employed
12 by any of the parties to the action in which these
13 proceedings were taken, and further that I am not a
14 relative or employee of any attorney or counsel
15 employed by the parties thereto, nor financially or
16 otherwise interested in the outcome of the action.

17
18 My commission expires: April 14, 2000

19

20



21

Notary Public in and for
the District of Columbia

22



1825 K Street, N.W.
Suite 1212
Washington, D.C. 20006
(202) 429-0014 (202) 429-0015

ERRATA SHEET

Please print or type the vital information below.

Case Name: Eric A. Forssen v. Rolf J. Mehlhorn

Witness Name: James H. Prestegard

Deposition Date: 13 May, 1997

Review your transcript and make any changes and/or corrections upon this page, not on the transcript itself. Sign and date the bottom of this page and return it to our office so that it may be attached to the original transcript.

<u>Page No.</u>	<u>Line No.</u>	<u>Change and/or Correction</u>	<u>Reason Therefor</u>
37	3	insert comma after "preparations"	clarity
39.	11	insert after "in" -- either of --	clarity

MY COMMISSION EXPIRES 12/31/97

James H. Prestegard
Signature

5/21/97
Date

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

ERIC A. FORSSEN

v.

ROLF J. MEHLHORN

)
)
)
)
)

Interference No. 103,469

Administrative Patent Judge:
Ronald H. Smith

BOX INTERFERENCE
Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

FORSSSEN NOTICE UNDER 37 C.F.R. § 1.673(e)

In accordance with 37 C.F.R. §§ 1.673(e) and 1.673(g), junior party Forssen et al.

("Forssen") hereby certifies that Forssen and senior party Mehlhorn ("Mehlhorn") conducted an oral conference under C.F.R. § 1.673(g), and agreed on mutually acceptable times and places for commencing depositions for cross-examination as follows:

1. The deposition of J. Wylie Nichols is scheduled to be held on May 9, 1997, beginning at 10:00 AM at:

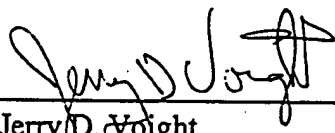
Finnegan, Henderson, Farabow, Garrett & Dunner, L.L.P.
1300 I Street, N.W., Suite 700
Washington, D.C. 20005

2. The deposition of James H. Prestegard is scheduled to be held on May 13, 1997,
beginning at 10:00 AM at:

Finnegan, Henderson, Farabow, Garrett & Dunner, L.L.P.
1300 I Street, N.W., Suite 700
Washington, D.C. 20005

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

By: 
Jerry D. Voight
Registration No. 23,020

Dated: April 28, 1997

Attorney Docket No. 03036.8051-00000

CERTIFICATE OF SERVICE

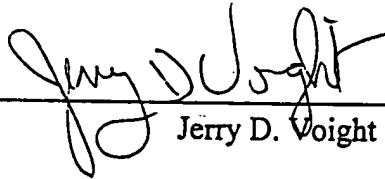
I hereby certify that a copy of the foregoing FORSSEN NOTICE UNDER 37 C.F.R. §

1.673(e), was served on April 28, 1997, by facsimile and first-class mail on

R. Danny Huntington, Esquire, lead attorney of record for the party Mehlhorn et al., at the

following address:

Burns, Doane, Swecker & Mathis
George Mason Building
699 Prince Street
Alexandria, Virginia 22314



Jerry D. Voight